this section. Also, if the Commissioner considers that investigations other than examination of such samples are necessary to determine whether or not such batch complies with the requirements of §431.10 for the issuance of a certificate, the fee shall include the cost of such investigations.

(f) The unearned portion of any advance deposit shall be refunded to the depositor upon his application.

(g) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under §433.12 of this chapter.

(h) All deposits and fees required by the regulations in this chapter, shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, DC. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health and Human Services, Accounting Branch (HFA–120), 5600 Fishers Lane, Rockville, MD 20857, whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasurer of the United States, for deposit to the special account ''Salaries and Expenses, Certification, Inspection, and Other Services, Food and Drug Administration.''

[39 FR 18934, May 30, 1974, as amended at 40 FR 13497, Mar. 27, 1975; 40 FR 28052, July 3, 1975; 41 FR 2384, Jan. 16, 1976; 41 FR 18291, May 3, 1976; 44 FR 67113, Nov. 23, 1979; 45 FR 16471, Mar. 14, 1980; 46 FR 16677, Mar. 13, 1981; 46 FR 60578, Dec. 11, 1981; 46 FR 61071, Dec. 15, 1981; 50 FR 19918, May 13, 1985; 55 FR 11582, Mar. 29, 1990]

Subpart C—Records and Reports

§431.61 Records of distribution.

(a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than 3 years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§431.62 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 431, photostatic or other permanent reproductions may be substituted for such records after the first 2 years of the holding period.

Subpart D—Confidentiality of Information

§431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

(a) The existence of an IND notice for an antibiotic drug will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an IND file for an antibiotic drug shall be handled in accordance with the provisions established in §314.430 of this chapter.

(c) Notwithstanding the provisions of §314.430 of this chapter, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational antibiotic has been used a copy of any adverse reaction report relating to such use.

[39 FR 44655, Dec. 24, 1974, as amended at 50 FR 7517, Feb. 22, 1985]